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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/658,734	09/11/2000	Winfried Edelmann	WYBI-0011	9039
23377	7590	08/03/2006	EXAMINER	
WOODCOCK WASHBURN LLP ONE LIBERTY PLACE, 46TH FLOOR 1650 MARKET STREET PHILADELPHIA, PA 19103			DAVIS, RUTH A	
			ART UNIT	PAPER NUMBER
			1651	

DATE MAILED: 08/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/658,734	Applicant(s) EDELMANN ET AL.	
	Examiner Ruth A. Davis	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 May 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 31-35, 45-55 and 68-71 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 68-71 is/are allowed.
- 6) ☒ Claim(s) 31-35 and 45-55 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. <u>20060728</u> . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____. | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

Applicant's amendment and response filed on May 10, 2006 has been received and entered into the case. Claims 13, 29, 30, 36 – 43 and 57 – 67 are canceled; claims 31 – 35, 45 – 55 and 68 – 71 are pending and have been considered on the merits. All arguments have been fully considered.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 34 – 35 and 45 – 55 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods for identifying compounds that inhibit meiosis, or stimulate/inhibit chromosome synapsis in a cell, does not reasonably provide enablement for identifying compounds that are useful for preventing fertilization or contraception. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The claims are drawn to methods for identifying compounds that prevent fertilization and contraception, however the specification only teaches identifying compounds that affect meiosis and chromosome synapsis. The specification identifies that mice with mutant MSH5 are not

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fertile and that MSH5 regulates meiosis and is necessary therefore. However the specification fails to teach one in the art how these compounds are necessarily useful as contraceptives, or in preventing fertilization. The specification neither provides examples of these compounds nor examples of their effectiveness. Thus the specification fails to enable one in the art how to make, use and practice the claimed invention.

Applicant argues that the specification outlines how to assess for preventing fertilization and provides examples showing that mice with mutated MSH5 have symptoms of infertility. Applicant points to pages 7 and 14 for support. Applicant further argues that it is not necessary to disclosed examples of compounds which would prevent fertilization.

However, the pages relied upon by applicant tests for agents that bind MSH5, not agents that prevent fertilization. Thus, the specification evaluates compounds that may be useful in fertility treatment, not compounds that will prevent fertilization. Furthermore, the specification teaches animals with defective mutations in the MSH5 gene will exhibit fertility problems, not whether or not a compound will effectively and positively prevent fertilization. Thus, the teachings of the specification fail to teach one in the art how to identify an effective agent for preventing fertilization. Furthermore, while applicant is not required to identify all compounds that may be identified by the claimed method, the specification must be enabled to identify at least one compound that will prevent fertilization. The specification is absent any teachings that the claimed method will positively identify such a compound. It is maintained that undue experimentation is required by one in the art to identify such a compound since the specification

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fails to give a basic structure, or even starting point, for discovering what compound may or may not prevent fertilization.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 31 – 33 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Hollingsworth.

Applicant claims methods for identifying compounds for inhibiting meiosis. The methods comprise contacting MSH5 protein, or a cell expressing MSH5 gene with the candidate compound, determining activity or expression of MSH5 in the presence of the compound,

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selecting a compound that inhibits MSH5, and identifying the compound useful for inhibiting meiosis. The cells is an oocytes or spermatocyte.

Hollingsworth teaches that MSH5 is meiosis specific gene that is active to facilitate meiosis (abstract) in bacteria, yeast, and humans (p.17290. Hollingsworth additionally teaches that mutant MSH5 (or inhibited activity thereof) results in decreased spore viability (p.1735-6). Thus, Hollingsworth suggests that inhibited or reduced activity of MSH5 inhibits meiosis and decreases fertility.

Although the reference does not teach specific methods for identifying compounds that would inhibit meiosis, Hollingsworth clearly suggests that MSH5 is critical to meiosis activities. Given the teachings of Hollingsworth it would have been obvious to assay for a candidate for meiotic inhibitor, by testing putative agents for their ability to inhibit MSHS. Thus, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to assay for such compounds, especially in the absence of evidence to the contrary.

Response to Arguments

Applicant argues that the reference does not teach MSH5 is meiosis specific, facilitates meiosis, or is critical to meiosis. Applicant further asserts that the examiner has taken "official notice" and requests supporting evidence.

However, these arguments fail to persuade because the reference clearly teaches that the MSH5 gene facilitates meiosis in that mutations in the gene have reduced spore viability. Thus the reference demonstrates that meiosis is inhibited. Furthermore, the reference likens MSH5

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mutants to MSH4 mutants and states that they are likely to function in a similar process (abstract). The reference goes on to say that MSH5 works to facilitate meiotic recombination between homologs (p.1735). Regarding applicants assertion that the examiner has taken official notice, it is noted that the examiner has not taken official notice as described by MPEP 2144.03. The examiner has cited and relied upon the teachings of Hollingsworth as indicated in the rejection and response above, to demonstrate that it was known in the art that MSH5 was known to facilitate meiosis (pages 1735-36). Moreover, Hollingsworth clearly teaches mutant MSH5 genes exhibit defective meiosis recombination (p.1729) and decreased spore viability (p.1735). Thus the reference clearly evidences that at least half of the spores are not viable, or wherein meiosis was inhibited. For these reasons, the claims stand rejected.

Allowable Subject Matter

6. Claims 68 – 71 are allowed.

During an interview with Janet Reed on or about July 27, 2006, claims 68 – 71 were indicated allowable and the examiner request that non-allowable subject matter be canceled. However, agreement to the claims could not be met.

Conclusion

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth A. Davis whose telephone number is 571-272-0915. The examiner can normally be reached on M-F 7:00 - 2:30pm.

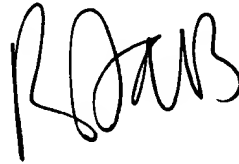
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ruth A. Davis
Primary Examiner
Art Unit 1651

July 28, 2006

A handwritten signature in black ink, appearing to read 'RDavis', is located below the printed name and title of the primary examiner.